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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,715	01/12/2000	CLARE PASSMORE	6442/60557	7077

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,715

Applicant(s)

PASSMORE ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,23 and 25-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20,23 and 25-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 1-20, 23, 25-37 are pending. The Amendment filed 1/2/03, Paper No. 13, amended claims 1, 9, 14, 23, 31, and 34-36.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 1/2/03 (Paper No. 13) to the rejection of claims 1-20, 23, 25-37 made by the Examiner under 35 USC 103 and 112, first paragraph, have been fully considered and deemed not persuasive.

The Applicant's amendment filed 1/2/03, Paper No. 13, is sufficient to overcome the 35 USC 112, second paragraph, rejections in the previous Office Action.

112 Rejection Maintained

The rejection of claims 1-20, 23, 25-37 under 35 U.S.C. 112, 1st paragraph is MAINTAINED for the reasons set forth in the Office Action mailed 7/2/02, Paper No. 12, and those found below.

Applicant argues, "Applicants, however, are not claiming new drugs or 'pharmaceuticals' which require testing of physiological activity, but rather a new composition of known pharmaceuticals". This argument is not persuasive. Pharmaceutically active agents encompass an incredible number of compounds, wherein different compounds have vastly different structures and properties. Thus, it would be impossible for one skilled in the art to mix an incredible number of pharmaceutical combinations to arrive at Applicant's invention.

Applicant argues, "The known pharmaceuticals contemplated for use in applicants' invention have known 'physiological activity'. This argument is not persuasive, as independent claim 1 encompasses any combination of pharmaceuticals.

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103 Rejection Maintained

The rejection of claims 1-9, 11, 12, 14-20, 25-37 under 35 U.S.C. 103(a) as being unpatentable over US 5,206,021 is MAINTAINED for the reasons set forth in the Office Action mailed 7/2/02, Paper No. 12, and those found below.

Applicant argues, “applicants, wish to clarify that their composition is formulated for enhanced ‘transdermal permeation’”. This argument is not persuasive, as the recitation “for mutual enhancement of transdermal permeation” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant argues, “applicants. . . provided a definition of the term ‘pharmacological agent’. . . the term is defined as an ‘agent used in prophylaxis or therapy of any condition affecting the health of the human or animal species.’ Of note are the terms ‘prophylaxis’ and ‘therapy’ which cannot include pesticides because pesticides are clearly detrimental to human and animal health”. This argument is not persuasive. First, the Examiner respectfully points out that antifungal agents and antibacterial agents, such as those taught by US ‘021, are pharmacological agents as defined by Applicant’s definition. Second, the Examiner respectfully points out that insects are animals. See the definition of “animals” in Webster’s Dictionary or see a general biology text that defines the Kingdom Animalia.

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Applicant argues, "The agents of the '021 patent are not drugs as defined in applicants' specification. Indeed, many of the '021 agents are toxic to humans, hence the widespread concern about pesticide toxicity and damage to human health". This argument is not persuasive. First, the Examiner respectfully points out that US '021 specifically teaches etaconazole and nitrofen, compounds which the instant invention defines as drugs or pharmacologically active agents. The Examiner respectfully points out that a compound and its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). While '021 does not state these compounds as drugs or pharmacologically active agents, they inherently have this property. Second, the Examiner respectfully points out that most drugs can cause damage to human health. It is for this reason that drugs are prescribed in certain dosages often based on a person's size.

Applicant argues, "It is well settled that terms in a claim should be interpreted using the specification. According to applicants' specification, it is clear that applicants' use of the term 'pharmacologic' or 'pharmacologically' excludes the pesticides of the '021 patent". This argument is not persuasive. Is Applicant saying that etaconazole and nitrofen are not pharmacologic? Again, the Examiner respectfully reminds Applicant that a compound and its properties are inseparable.

Applicant argues, "Applicants' method claims. . . recite a 'method for mutual enhancement of dermal permeation', which method is certainly not applicable for use with pesticides". This argument is not persuasive. The Examiner respectfully points out that the composition itself has the property of 'mutual enhancement of dermal permeation' when applied to the body surface of an animal. Thus, when the pesticide is applied to the body of pests, which are animals, 'mutual enhancement of dermal permeation' is achieved.

Applicant argues, "The term 'body surface' clearly means, in the context of this application, the human or animal body. Thus, the Examiner's linking of the '021 patent, where the pesticidal compositions are applied to crops, cannot be relevant prior art". This argument is not persuasive. Again the Examiner respectfully points out that a) topical application of the composition to crops would result in topical application to the pests, which would lead to penetration of the pesticides into the pests, and that b) insects are animals. Furthermore, the Examiner respectfully points out that pesticidal compositions are also topically applied to humans for the same purpose.

The rejection of claims 1-12, 14-20, 25-37 under 35 U.S.C. 103(a) as being unpatentable over US 5,206,021 , and further in view of either the USPATFULL abstract of US 5525597 or the CAPLUS abstract of WO 9518122 is MAINTAINED for the reasons set forth in the Office Action mailed 7/2/02, Paper No. 12, and those found below.

Applicant argues, "The 597 document and the 122 document neither disclose nor suggest the use of therapeutic or prophylactic agents. . .both the 597 document and the 122 document neither disclose nor suggest the use of eutectic mixtures to achieve mutually enhanced permeation of any agent, must less therapeutic or prophylactic agents". This argument is not persuasive. First, the Examiner respectfully points out '597 and '122 are relied upon to teach preferred active agents, and that the primary reference is relied upon to teach the method and the eutectic mixtures. By stating that 597 and 122 neither disclose nor suggest the use of therapeutic or prophylactic agents, is Applicant stating that capsaicin, as taught by 597, and triclosan, as taught by '122, are not therapeutic or phrophylactic agents? The Examiner respectfully points

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out that triclosan and capsaicin are recited as therapeutic/phrophylactic agents in the instant specification, and that a compound and its properties are inseparable.

The rejection of claims 1-9, 11-20, 25-37 under 35 U.S.C. 103(a) as being unpatentable over US 5,206,021, and further in view of The Condensed Chemical Dictionary is MAINTAINED for the reasons set forth in the Office Action mailed 7/2/02, Paper No. 12, and those found below.

Applicant argues, "neither lauric acid nor cinnamic acid is a prophylactic or a therapeutic agent". This argument is not persuasive. Again, The Examiner respectfully points out a compound and its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)).

Notes/Suggestion

Regarding claims 9 and 34, The Examiner respectfully points out that for the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to comprising. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of', applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

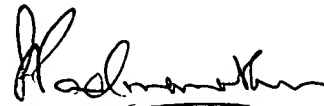
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
March 3, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER
3/2/03